Testimony of

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Before the Subcommittee on Emergency Preparedness, Science and Technology of the
Committee on Homeland Security,
United States House of Representatives

Regarding

"Project BioShield: Linking Bioterrorism Threats and Countermeasure Procurement to Enhance Terrorism Preparedness"

July 12, 2005

My name is Michael Greenberger.

I want to thank the subcommittee for inviting me to testify on the important issue that is the subject of today's hearings.

From 1999 to 2001, I served as Justice Department's Principal Deputy Associate Attorney General. Included within my portfolio of responsibilities were several counterterrorism projects concerning both law enforcement and public health policy, including organizing the first nationwide counter terrorism field exercise, "TOPOFF I."

I now serve as a Law School Professor at the University of Maryland School of Law and, since May 2002, as the Director of the University of Maryland Center for Health and Homeland Security.

At the School of Law, I have designed and teach two courses focused on legal and public policy issues concerning counterterrorism: (1) "Homeland Security and the Law of Counterterrorism," which addresses the legal framework surrounding the response to the terrorist threat facing the United States, including the Project Bioshield Act of 2004; (2) "Homeland Security – The Interdisciplinary Study of Crisis and Health Consequence Management Policy in the Era of Counterterrorism" which is open to students from all of the University of Maryland professional schools and explores public health policy implications of counterterrorism strategy, including the development of a stable biodefense vaccine industry.

The University of Maryland Center for Health and Homeland Security (CHHS) serves as an advisor on public health emergency planning to various state and local agencies. CHHS also works closely with: (1) the Center for Vaccine Development (CVD) at the University of Maryland School of Medicine, which is the only university vaccine center in the world engaged in the full range of vaccinology: from basic science through vaccine development, clinical evaluation and field studies, including groundbreaking work on biodefense vaccines; and (2) the Mid-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE), one of eight Regional Centers of Excellence (RCE) funded by the National Institute of Allergy and Infectious Diseases (NIAID). MARCE is headed by Dr Myron Levine, the director of CVD. MARCE is now in the process of researching and developing new biodefense vaccine products to be used as prophylaxis against a broad array of biological agents.

Through CHHS's work with CVD and MARCE, CHHS has organized symposia[1] and I have written several articles[2] addressing the substantial economic, regulatory, and legal roadblocks to creating biodefense vaccines.

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[1] Symposium, *Eliminating Legal, Regulatory, and Economic Barriers to Biodefense Vaccine Development*, at the University of Maryland School of Law, June 9, 2004.

[2] Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7 (2005) (hereinafter Greenberger, *800 Pound Gorilla*); Michael Greenberger, et al., *The Threat of Smallpox: Eradicated but not Erased*, J. HOMELAND SEC, Feb. 2004, http://www.homelandsecurity.org/journal/Articles/displayarticle.asp?article=103; ELIN GURSKY & MICHAEL GREENBERGER, ANSER INSTITUTE FOR HOMELAND SECURITY, INSTITUTE COMMENTARY: SUPPOSE THEY GAVE A

One of the bright milestones toward the development of a vibrant biodefense vaccine industry was the passage of the Project BioShield Act of 2004. That statute was designed "to provide protections and countermeasures against chemical, radiological, or nuclear [CBRN] agents that may be used in a terrorist attack against the United States."[3] The most prominent parts of that legislation were its procurement provisions designed to address the key significant impediment to biodefense vaccine production, lack of a significant market.[4] These provisions encourage the development of effective vaccine countermeasures by establishing a Special Reserve Fund of $5.6 billion to be spent over the next ten years to purchase for the Nation's Strategic National Stockpile (SNS) the "next generation of countermeasures against" a broad array of chemical, biological, radiological, and nuclear agents, all of which were seen by Congress as weapons that could be deployed against the United States in the War on Terror.[5] Due to the substantial expense and risk of bringing a vaccine to market, along with the infrequency with which these diseases occur naturally, pharmaceutical manufacturers have little to no incentive to invest without BioShield funds.[6]

In order for the Bioshield Special Reserve Funds to be released for the purchase of a countermeasure for SNS, a series of actions must occur.[7] However, the first action (and the one on which all later actions are based) is that "the Homeland Security [DHS] Secretary, in consultation with the [HHS] Secretary and the heads of other agencies as appropriate," must make a "determination" of "current and emerging threats of CBRN agents" that "present a material threat against the United States . . ."[8] Once that "material threat assessment" is made various government agencies, up to and including, the President, through a series of decisions then determine whether promising countermeasures may be purchased with the special reserve funds to address those identified threats.[9]

The BioShield Act established no procedure for DHS to employ in supervising the making of the material threat determinations. Despite what was an obvious Congressional invitation to summarily determine what are the widely recognized CBRN threats to the United States, DHS has employed an opaque, highly bureaucratized, relatively lengthy process for determining material threats. Over the course of the past year, this cumbersome and poorly

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CIVILIAN SMALLPOX VACCINATION PROGRAM—AND (ALMOST) NOBODY CAME? (Feb. 20, 2004), http://www.homelandsecurity.org/Hls/commentary/gursky_smallpox_commentary_20feb04.html.

[3] Project BioShield Act, Pub. L. 108-276, 118 Stat 835 (2004).

[4] Frank Gotron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1.

[5] United States Department of Health and Human Services, HHS Fact Sheet – Project BioShield, July 21, 2004, http://www.hhs.gov/news/press/2004pres/20040721b.html

[6] *Bioshield: Countering the Bioterrorist Threat: Hearing Before the House Select Committee on Homeland Security*, 108th Cong. (May 15, 2003) (statement of Alan Pemberton, Pharmaceutical Research and Manufacturers of America), *available at* http://www.globalsecurity.org/security/library/congress/2003_h/5-15-03_pharmaceutical.pdf; Frank Gotron, *Project BioShield*, CRS REP. NO. RS21507 (Updated December 27, 2004), at 1-2.

[7] Project BioShield Act of 2004, Pub. L. 108-276, § 3(a)(2), 118 Stat. 835,843-52 (2004); United States Department of Health and Human Services, Procurement Items – BioShield Funds, March 23, 2005, http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html.

[8] Project BioShield Act of 2004, Pub. L. 108-276, § 3(a)(2), 118 Stat. 835, 844 (2004).

[9] Project BioShield Act of 2004, Pub. L. 108-276, § 3(a)(2), 118 Stat. 835, 843-48 (2004); United States Department of Health and Human Services, Procurement Items – BioShield Funds, March 23, 2005, http://www.hhs.gov/ophep/bioshield/bioshieldfunds.html.

delineated administrative process has led to only four material threat determinations. Findings have been made that Anthrax, Smallpox, Botulinum toxin and radiological/nuclear devices pose a material threat to the United States. DHS officials have promised that by the close of this fiscal year material threat determinations will be made concerning plague, tularemia, and viral hemorrhagic fevers.[10]

Because there have only been material threat determinations pertaining to four CBRN agents, BioShield's Special Reserve funds can only be used for countermeasures directed to those agents. Accordingly, three contracts have been let over this last year, two directed to the purchase of anthrax vaccines[11] and one for the delivery of pediatric doses of liquid potassium iodide.[12] Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement if there were no corresponding finding that the agent to which it was directed was a "material threat."

DHS's lassitude in supervising the making of material threat findings is mystifying. The legislative history of the statute is replete with references to a myriad of agents, beyond the four agents identified, posing a substantial threat to the United States.

Moreover, the Center for Disease Control (CDC) has a long established and widely recognized hierarchy of highly damaging biological agents that are likely to be deployed by terrorists against the United States. CDC's Category A agents, ranked as the most dangerous to the United States, include Anthrax, Botulism, Plague, Smallpox, Tularemia, and Viral hemorrhagic fevers. Only three of those agents have as yet been identified under the BioShield bureaucracy as posing a material threat. DHS has assured committees of Congress that it will by the end of this fiscal year make findings on the remaining three Class A agents identified by CDC.

When you look at the Category B and C agents identified by CDC, there are total of more than 33 agents which ultimately will need to be addressed with medical countermeasures.[13] At the rate the "material threat" findings have been made to date, it could be years before BioShield procurement funds can be used to purchase products designed to counter the as yet undesignated agents.

Leaving CDC's findings to the side, scholarship on terrorist threats abound with long standing and well recognized findings about a significant number of CBRN agents likely to be

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[10] *Combating Weapons of Mass Destruction: Hearing Before the Subcommittee on National Security, Emerging Threats, and International Relations of the H. Comm. Of Government Reform*, 109th Cong. (June 15, 2005) (testimony of Dr. John Vitko, Jr.. Director, Biological Countermeasures Portfolio, Science and Technology Directorate, Department of Homeland Security), *available at* http://reform.house.gov/UploadedFiles/ST.Govt%20Ref.Vitko.06-14-05.pdf.

[11] Press Release, United States Department of Health and Human Services, HHS Buys New Anthrax Vaccine for Stockpile (Nov. 4, 2004), http://www.hhs.gov/news/press/2004pres/20041104a.html; Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for AVA Anthrax Vaccine (May 6, 2005), http://communitydispatch.com/artman/publish/article_961.shtml.

[12] Press Release, United States Department of Health and Human Services, HHS Awards BioShield Contract for Liquid Potassium Iodide (March 18, 2005), http://www.hhs.gov/news/press/2005pres/20050318.html.

[13] CDC, Bioterrorism Agents/Diseases (Nov. 19, 2004), http://www.bt.cdc.gov/agent/agentlist-category.asp.

deployed against the United States. For example, Jessica Stern in her 1999 classic, The Ultimate Terrorists, lists two dozen chemical agents that have been historically deployed by terrorists going all the back to World War I.[14] Not one of these chemical agents has been certified under DHS' leadership. Nor has DHS even committed to making such designations in the future.

Quite ironically, under other provisions of the BioShield statute concerning HHS funding for research (which does not require a "material threat" finding), grants have been made for the development of countermeasures relating to tularemia, Ebola, and plague.[15] Yet, none of these agents has yet been designated as a material threat. If HHS has already commenced funding for research in this area, one would assume that there is substantial evidence available to DHS demonstrating that these agents should be so designated.

From CHHS own experience, substantial NIH funding outside of the BioShield appropriations is being committed to the development of medical countermeasures not yet declared to be "material threats". For example, MARCE is researching countermeasures for tularemia as part of a five-year, grant from NIAID, which is supported by funding wholly apart from monies appropriated under the BioShield statute.[16] Simultaneously, plague vaccine research is being performed in the laboratories of James Nataro, M.D. at the CVD that is funded by funded by a National Institutes of Health U19 grant,[17] again a project being done wholly apart from the BioShield Act.

The BioShield Act is an impressive starting point for the creation of a vibrant biodefense vaccine industry. It has many problems that must be corrected both administratively and legislatively.[18] I would be happy to address each of those issues with you today. However, only one of those problems deals directly with DHS, the agency over which you have direct oversight responsibilities. DHS bureaucratic quagmire in identifying CBRN agents posing a material threat to the United States (thereby delaying the use of procurement efforts for well recognized CBRN dangers to this country) is a matter that deserves your full attention.

This problem does not require a legislative fix. What it requires is prodding the agency to abandon an administrative morass. It requires directing the agency to follow the well worn path already trodden through scholarship and the work of the CDC to quickly list the full panoply of CBRN agents. Such an expedited effort would be an encouragement to both researchers and the vaccine industry that a broad array of efforts might be funded over the next decade by the BioShield Special Reserve Fund.

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[14] JESSICA STERN, THE ULTIMATE TERRORISTS 24-25 (1999).

[15] Press Release, United States Department of Health and Human Services, NIH News, NIAID Awards First $27 Million Using New Bioshield Authorities (May 9, 2005), http://www.nih.gov/news/pr/may2005/niaid-09.htm.

[16] Virginia Bioinformatics Institute, Mid-Atlantic Regional Center of Excellence, https://www.vbi.vt.edu/article/view/426.

[17] Center for Vaccine Development, University of Maryland School of Medicine, Nataro Lab, http://medschool.umaryland.edu/cvd/natarolab/natarolab.html

[18] For a complete description of the problems with implementing the BioShield statute, *see Crossing the Valley of Death: Bringing Promising Medical Countermeasures to BioShield: Hearing Before the Senate Health, Education, Labor and Pensions Subcommittee on Public Health*, 109th Cong. (June 9, 2005) (statement of Dr. Phillip Russell, Major General, Retired, U.S. Army), http://help.senate.gov/testimony/t319_tes.html. I agree with almost all of Dr. Russell's assessments. For a proposal to resolve indemnification problems identified by Dr. Russell and others, *see* Greenberger, *800 Pound Gorilla, supra* note 2.

Finally, this subcommittee should be aware that the legislation recently introduced as a corrective to the Bioshield Act (S. 975, or the Project Bioshield II Act of 2005) places the major procurement responsibility principally in the hands of DHS, reducing substantially the role of HHS.[19] This displacement of HHS is supposedly called for because industry supporters of Bioshield II view "HHS as having a contentious relationship with the biopharma industry."[20] However, given the difficulties DHS has had with effectively carrying out its single major mission under the existing legislation, Congress should think long and hard before it puts the entire biodefense vaccine apparatus under DHS.

[19] ARNOLD & PORTER, LLP., CLIENT ADVISORY: "BIOSHIELD II" BILL WOULD EXPAND INCENTIVES TO DEVELOP BIODEFENSE COUNTERMEASURES 1 (May 2005), http://www.arnoldporter.com/pubs/files/A&PAdvisory-BioshieldII(0505).pdf.
[20] *Id.* at 2.

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Testimony Summary

The Department of Homeland Security has employed an opaque, highly bureaucratized, and lengthy process under the Project Bioshield statute for determining those chemical, biological, radiological and nuclear (CBRN) agents which pose "material threats" to the United States. BioShield's Special Reserve funds can only be used for countermeasures directed to those agents designated by DHS as material threats. DHS's decision-making apparatus has to date only made material threat determinations pertaining to four CBRN agents. It is well understood both within the Center for Disease Control and in the scientific research community that there are as many a 60 agents that now pose a "material threat." Even if a promising countermeasure were to meet the other requirements for purchase under the statute, it would not be eligible for procurement because of a lack of a material threat finding. At the rate the "material threat" findings have been made to date, it could be years before funds will be eligible to purchase products designed to counter those as yet undesignated agents. Moreover, the delay in recognizing agents as a material threat amounts to a disincentive to both researchers and the vaccine industry to devote resources to CBRN agents that are not as yet designated as material threats.